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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,446	05/23/2006	Yvonne Armitage	BT/3-22350/A/PCT	4199

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JoAnn Villamizar
Ciba Corporation/Patent Department
540 White Plains Road
P.O. Box 2005
Tarrytown, NY 10591

EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,446	ARMITAGE ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/23/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 (preliminary amendment 5/23/2006) are pending and under examination.

Information Disclosure Statement

The information disclosure statement filed 9/06/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been fully considered.

Please, provide for the instant file the missing foreign patent documents and one missing NPL publication as indicated on PTO FORM 1449 form attached.

Specification

The disclosure is objected to because of the following informalities:

The current address of depository collection NCIMB is missing (specification page 11).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Deposit

Claim 10 is rejected under 35 U.S.C. 112, *first paragraph,* as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism *Rhodococcus rhodochrous* NCIMB 41164. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the

specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because NCIMB has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

Indefinite

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase "none actively growing free cells". The meaning of the phrase is uncertain in the lack of definitions in the as-filed specification.

Claims 2 and 3 recite that "microorganisms is recovered" but they do not clearly points out when in the sequence of the active steps of the method of claim 1 these steps take place.

Claim 4 recites that "microorganisms is retained" but does not points out when in the sequence of the active steps of the method of claim 1 this step takes place.

Claim 5 is rendered indefinite by the phrase "preferably". A broad range or limitation followed by linking terms and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. MPEP 2173.05(c).

Claim 6 recites the limitation "the components" of different media recited in claim 1. There is insufficient antecedent basis for this limitation in the claim since claim 1 recites at least 3 different media (a growth medium, an aqueous medium, a storage medium that comprise water) and it does not point out any specific components except for water.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,705,382 (Endo et al).

Claims are directed to a method of producing an amide from the corresponding nitrile wherein the method comprises steps i) providing a microorganism capable of producing a nitrile hydratase biocatalyst, ii) culturing the microorganism in a growth medium, iii) storing the microorganism, iv) contacting the nitrile with the microorganism in an aqueous medium and thereby converting the nitrile to the amide, wherein the microorganism is stored as "none actively growing free" cells in a storage medium that comprises water. Some claims are further drawn to producing amide such as acrylamide. Some claims are further drawn to the use of same or different components in the growth medium and in the storage medium. Some claims are further drawn to the medium components being water, physiological saline, buffer or urea. Some claims are further drawn to the use of storage temperature being above the freezing point of the storage medium. Some claims are further drawn to the storage period for 2 days and more. Some claims are further drawn to the use of microorganism belonging to the genus of *Rhodococcus* or to the species of *Rhodococcus rhodochrous*.

US 5,705,382 (Endo et al) discloses a method of producing an amide from the corresponding nitrile (entire document including particular example 4 at col. 6-7) wherein the method comprises steps i) providing a microorganism belonging to the genus of *Rhodococcus* that is capable of producing a nitrile hydratase biocatalyst, ii) culturing the microorganism in a growth medium, iii) storing the microorganism, iv) contacting the nitrile with the microorganism in an aqueous medium and, thereby, converting the nitrile to the amide, wherein the microorganism is stored as a cell suspension or as "none actively growing free" cells in a storage medium that comprises water and/or phosphates. In the particular example 4, the microorganism is recovered from growth medium; both growth medium and storage medium comprises water

and phosphates or physiological saline and/or buffer; the storage temperature is above the freezing point or 20 degree C; the storage period is about 100 days or more than 2 days (col. 7, lines 1-6). The cited patent also teaches that the microorganisms can be stored either as free cell suspension or as immobilized cells (col. 1, lines 54-65) in the method for producing amide. The cited patent also teaches producing amide such as acrylamide (col. 8, line 27). The cited patent also teaches the use of representative of the species of *Rhodococcus rhodochrous* (col. 2, line 37 or example 6) in the method for producing amide wherein the method comprises incorporation of urea in growth medium (col. 7, line 61) and storing cells as "non-actively growing" immobilized cells.

Thus, the cited method comprises identical steps and identical structural elements as required by the claimed method and, therefore, the cited patent US 5,705,382 anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,705,382 (Endo et al), Nagasawa et al (IDS reference. Pure and Appl. Chem. 1996, Vol. 67, No. 7, pages 1241-1256) and US 5,089,411 (Yamada et al).

Claims are directed to a method of producing an amide from the corresponding nitrile wherein the method comprises steps i) providing a microorganism capable of producing a nitrile

hydratase biocatalyst, ii) culturing the microorganism in a growth medium, iii) storing the microorganism, iv) contacting the nitrile with the microorganism in an aqueous medium and thereby converting the nitrile to the amide, wherein the microorganism is stored as "none actively growing free" cells in a storage medium that comprises water. Some claims are further drawn to producing amide such as acrylamide or methacrylamide. Some claims are further drawn to the use of same or different components in the growth medium and in the storage medium. Some claims are further drawn to the medium components being water, physiological saline, buffer or urea. Some claims are further drawn to the use of storage temperature being above the freezing point of the storage medium. Some claims are further drawn to the storage period for 2 days and more. Some claims are further drawn to the use of microorganism belonging to the genus of *Rhodococcus* or to the species of *Rhodococcus rhodochrous* or to the use of particular strain *Rhodococcus rhodochrous* NCIMB 41164.

The cited patent US 5,705,382 (Endo et al) is relied upon as explained above for the disclosure of a method for producing amides from the corresponding nitriles (entire document including particular examples 4 and 6) wherein the method comprises steps culturing microorganisms belonging to the genus of *Rhodococcus* including representatives of the species of *Rhodococcus rhodochrous* in a growth medium, storing the microorganisms in a storage medium and converting nitriles to amides by using enzymatic activity of microbial cells after prolonged storage at temperature above freezing point.

The cited patent US 5,705,382 is lacking particular disclosure about the use of specific strain *Rhodococcus rhodochrous* NCIMB 41164. However, it discloses another strain *Rhodococcus rhodochrous* such as strain J-1 (col. 7, line 59) that is capable for producing both

acrylamide (col. 8, line 27) and methacrylamide (see Nagasawa et al. at page 1248, lines 8-15) and that retains enzymatic activity after prolonged storage at temperature above freezing (col. 8, line 14 and table 6).

Although in the particular example *Rhodococcus rhodochrous* strain J-1 is immobilized before storage, the cited patent US 5,705,382 clearly teaches that microbial cells having nitrile hydratase including representatives of the genus *Rhodococcus* activity can be stored either as free cell suspensions or as immobilized cells (col. 1, lines 54-65) in the method for producing amide (examples 4 and 7).

The cited patent US 5,705,382 also teaches incorporation of urea in the culture medium for *Rhodococcus rhodochrous* (col. 7, line 61). Further, US 5,089,411 (Yamada et al) is relied upon for the explicit teaching that incorporation of urea and its derivates increases enzymatic activity of *Rhodococcus rhodochrous* (entire document including abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Rhodococcus rhodochrous* cells stored as free cell suspensions and to use urea in the culture media of *Rhodococcus rhodochrous* in the US 5,705,382 with a reasonable expectation of success in producing amide because the prior art teaches that microbial cells retain their having nitrile hydratase activity when stored either as free cell suspensions or as immobilized cells and because incorporation of urea and its derivates increases enzymatic activity of *Rhodococcus rhodochrous*. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The substitution of one strain for another microbial strain is considered to be substitution of equivalents in the instant case wherein the prior strain J-1 belongs to the same species and

capable to produce amide after storage as the claimed strain NCIMB 41164. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

May 9, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657